



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

OFFICE OF SHELLFISH PROGRAMS

7171 Cleanwater Ln., Bldg. 4 • P.O. Box 47824 • Olympia, Washington 98504-7824

(360) 236-3330 • TDD Relay Services 1-800-833-6388

April 15, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir or Madam:

This letter is in response to Docket No. 98P-0504, a petition from the Center for Science in the Public Interest (CSPI), dated June 29, 1998. The petition requests that the Food and Drug Administration (FDA) adopt regulations to control *Vibrio vulnificus* in molluscan shellfish.

The Interstate Shellfish Sanitation Conference (ISSC) is currently considering new restrictions on the commercial harvest and sale of shellfish likely to present a significant potential hazard to particularly susceptible consumers due to *V. vulnificus*. A proposed change to the National Shellfish Sanitation Program (NSSP) Model Ordinance was submitted to the ISSC in 1998 (Issue 98-106) and is being evaluated by a committee of that organization. The issue, as submitted, raised some questions that are not answerable at this time. We are aware that the FDA is conducting laboratory research that may soon answer those questions and provide a scientific basis for more effective control measures for several kinds of vibrios.

We request that FDA wait until its current research on *V. vulnificus* is complete and the ISSC process has had a chance to act on the research data before considering specific regulations to control the hazard. Adequate safety might be provided by a level of *V. vulnificus* in shellfish above "non-detectable" at harvest.

The vast majority of cases of illness from this agent associated with shellfish have been linked to oysters. Therefore, we believe that any performance standard should be specific to oysters.

We have no knowledge of any illness caused by *V. vulnificus* from shellfish confirmed to have been harvested in Washington State. We are aware of one fatal case that occurred in California in early May of 1995 where the source of implicated clams could not be confirmed. The market where the clams were obtained had clams from two sources: Washington State and Florida. We strongly object to the CSPI contention that, when the *V. vulnificus* source for a case cannot be determined, all states identified as suppliers of shellfish to the retail establishment associated

98P-0504

C159



Docket No. 98P-0504

April 15, 1999

Page Two

with the case have the burden to prove they were not the source. Any control measures should be directed at confirmed sources of infection.

We have confirmed that Washington State shellfish have been the source of infections due to *V. parahaemolyticus*. We believe that any performance standard for this agent should be developed separately from a performance standard for *V. vulnificus*. In 1998, the ISSC adopted an interim control plan for *V. parahaemolyticus* on a pilot basis for three years. The results will be evaluated for deliberation at the 2001 ISSC conference. Washington State implemented the control plan in the summer of 1998. We believe the ISSC is the appropriate organization to develop and implement control measures for wholesale shellfish operations to minimize illnesses caused by *V. parahaemolyticus*.

We appreciate the opportunity to comment on this petition and voice our concerns. Please contact me at (360) 236-3325 if there are any questions regarding these concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Tebaldi". The signature is fluid and cursive, with the first letter of the last name being a large, stylized 'T'.

Jennifer Tebaldi, Director
Office of Shellfish Programs

cc: Eric Slagle, Assistant Secretary, Environmental Health Programs



State of Washington
DEPARTMENT OF HEALTH
Office of Shellfish Programs
Airdustrial Center Building 4
PO Box 47824
Olympia WA 98504-7824



OLY P&DF, WA. 201

DOCKETS MANAGEMENT BRANCH HFA 305
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LN RM 1061
ROCKVILLE MD 20852

20857+0001

